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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,328	01/10/2008	**Abdul Waseh Basit**	33327.001	9321

25005 7590 03/14/2011

Intellectual Property Dept.
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EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/14/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,328	BASIT ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2011 and 25 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8,10-17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 8, 10-17, and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 14 January 2011 and 25 January 2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Applicant filed an information disclosure statement on 20 July 2006 which listed three separate non-patent literature documents. These documents were not considered because no documents were provided. Applicant provided the three documents in the response dated 25 January 2011. However, these documents are not legible, and as such, are not considered.

Claim Objections

Claims 5 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims depend upon claim 2, which has been cancelled. Applicant should amend the claim dependencies such that claims 5 and 6 depend only upon pending claims.

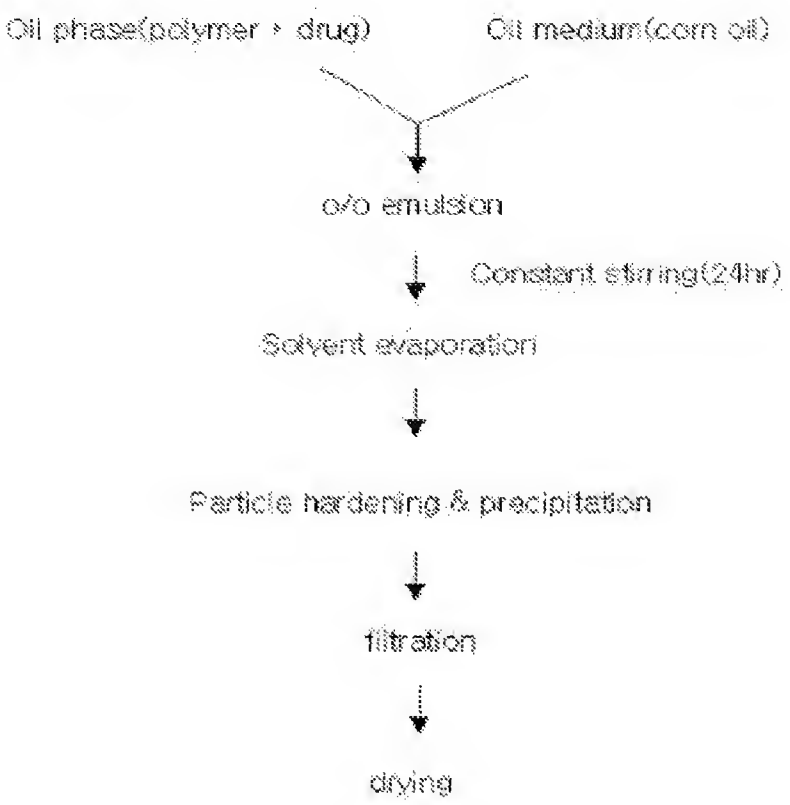
Claim 13 is objected to because of the following informalities: Claim 13 recites the word "orbudesonide." This appears to be a mis-spelling of the drug "budesonide."

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-6, 8, 10-13, 15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Journal of Microencapsulation, 2002, Vol. 19, No. 6, pages 811-822) in view of Hassan (US 2002/0119916) .

Kim et al. (hereafter referred to as Kim) teaches microspheres comprising the felodipine (a drug) which were prepared by an oil/oil emulsion evaporation method, as of Kim, page 811, abstract. In one embodiment, Eudragit RL and Eudragit RS (methacrylate copolymers as required by claims 1, 11, and 12) were dissolved in an acetonitrile/dichloromethane mixture then emulsified into corn oil using 2% Span 80 (polysorbate 80) as the surfactant, as of Kim, page 813, top two paragraphs, and page 1, Figure 1, reproduced below.



In the method of Kim, the particles made from said method are sized from 9.5 to 13.2 microns, as of Kim, page 811, abstract. Kim, when reviewing the prior art, teaches that systems comprising Eudragits are useful for the preparation dosage forms for oral administration, as of Kim, page 812, second full paragraph.

Kim does not teach “at least two surfactants”, as required by claim 1.

Hassan is drawn to a process of manufacture of particles for the delivery of water insoluble drugs, as of Hassan, abstract, wherein said process is an emulsion process. Hassan utilizes surfactants which may have a HLB value from 1 to 20, as of Hassan, paragraph 0019. Hassan suggests polyoxyethylene sorbitan fatty acids generically, which are known by Hassan as "Spans," as of Hassan, paragraph 0027. Sorbitan sesquioleate is a preferred surfactant of Hassan, as of paragraph 0027, and the

surfactant known by the trade name Arlacel 83 is suggested, as of Hassan, paragraph 0038, wherein the term Arlacel 83 is a trade name for sorbitan sesquiolate. The particles made by the method of Hassan are taught for oral administration, as of Hassan, page 5 claim 21. Hassan teaches various drugs including prednisone, as of Hassan, paragraph 0012.

It would have been prima facie obvious for one of ordinary skill in the art to have substituted the surfactants of Hassan for those of Kim. This is because the surfactants of Hassan are predictably known to be useful in an emulsion for oral administration with a reasonable expectation of success, wherein oral delivery suggested by Kim. The simple substitution of one known element (sorbitan sesquiolate, of Hassan) for another (Span 80, of Kim), to achieve predictable results (making an emulsion for oral administration) is prima facie obvious. See MPEP 2143, Exemplary Rationale B. Furthermore, Hassan teaches the entire genus of surfactants known by the trade name "span" (which includes the surfactant Span 80 of Kim), yet teaches that sorbitan sesquioleate is preferred, as of Hassan, paragraph 0027, which would have provided the skilled artisan with even greater motivation to have used sorbitan sesquiolate.

Arlacel 83, as taught by Hassan, paragraph 0038, reads on the requirement of claim 1 of “at least two surfactants” as it is a combination of sorbitan monoleate and sorbitan dioleate, as of page 6 lines 6-7 of the instant specification. Furthermore, the term Arlacel 83 is also known as sorbitan sesquiolate, as of page 7 line 7 of the specification and Hassan, paragraph 0038.

The above references do not specifically teach pH dependent release, as required by claim 8. However, the skilled artisan would have understood that the polymers used by Kim and Hassan, specifically the polymer known by the trade name Eudragit RS (as of Kim, abstract), would have possessed this property. The polymer known by the trade name "Eudragit RS" is recited by claim 11, and is disclosed by the specification at page 5 line 6. As such, the polymer known as Eudragit RS, which was used in the prior art, would have had the same properties.

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Journal of Microencapsulation, 2002, Vol. 19, No. 6, pages 811-822) in view of Hassan (US 2002/0119916) as applied to claims 1, 3-6, 8, 10-13, 15, and 20 above, and further in view of Perumal (International Journal of Pharmaceutics, Vol. 218, 2001, pages 1-11).

Kim teaches a method of making an oil in oil emulsion for drug delivery with a surfactant. Hassan teaches sorbitan sesquiolate as a said surfactant. See the above rejection.

The above references do not use ethanol as a solvent, as required by claim 14. Kim is silent as to the temperature at which emulsification occurs, as required by claim 16.

Perumal is drawn to an emulsion process for preparation of microspheres comprising the drug ibuprofen and the methacrylate polymer known by the trade name Eudragit RS 100. In said procedure, ibuprofen and the Eudragit polymer were initially

dissolved in ethanol, as of Perumal, page 2 left column section 2.2, bottom paragraph. The emulsification occurred in a thermally controlled room at about 20 degrees Celsius, as of Perumal, page 2 right column, top paragraph.

It would have been prima facie obvious for one of ordinary skill in the art to have used ethanol as the solvent to dissolve the drug and the Eudragit polymer in the procedure of the above references, as taught by Perumal. The skilled artisan would have been motivated to do so because ethanol is known to predictably act as a solvent for the combination of both the drug and the Eudragit polymer vehicle with a reasonable expectation of success, as the procedure of Perumal successfully produced microspheres.

It would have been prima facie obvious for one of ordinary skill in the art to have used a temperature of about 20 degrees Celsius (as taught by Perumal) in the procedure of the above references. The skilled artisan would have been motivated to do so because 20 degrees is taught to be a suitable temperature at which to make an emulsion, as taught by the procedure of Perumal. As such, the skilled artisan would have been motivated to have predictably made the emulsion of the above references at 20 degrees Celsius with a reasonable expectation of success.

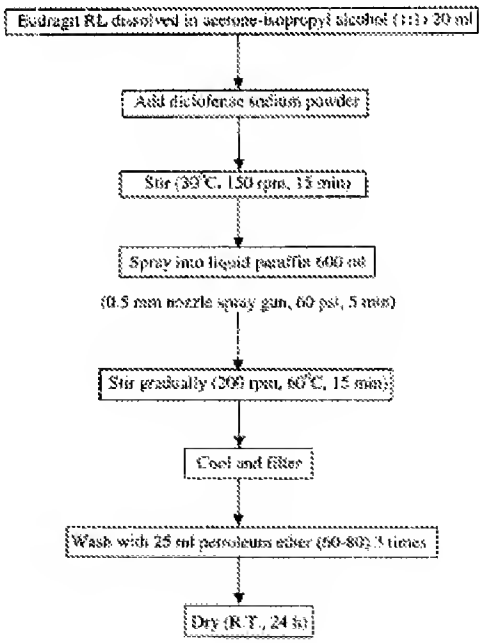
Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Journal of Microencapsulation, 2002, Vol. 19, No. 6, pages 811-822) in view of Hassan (US 2002/0119916) as applied to claims 1, 3-6, 8, 10-13, 15, and 20 above,

and further in view of Satturwar et al. (Journal of Microencapsulation, Vol. 19, No. 4, 2002, pages 407-413).

Kim teaches a method of making an oil in oil emulsion for drug delivery with a surfactant. Hassan teaches sorbitan sesquiolate as a said surfactant. See the above rejection. Corn oil is the continuous phase in Kim, as of Kim, Figure 1, reproduced in the above rejection.

The above references do not teach liquid paraffain. The above references do not teach an ethanol solvent system.

Satturwar et al. (hereafter referred to as Satturwar) is drawn to the preparation of Eudragit (polymethacrylate) microparticles, as of Satturwar, page 407, abstract. Said process utilizes acetone/isoproanol as the solvent and liquid paraffin as the continuous phase, as of Satturwar, page 408, Figure 1 (reproduced below).



It would have been prima facie obvious for one of ordinary skill in the art to have substituted the liquid paraffin phase of Satturwar for the corn oil phase of Kim. This is because both materials are predictably known to be used as continuous phases in methods of making emusions comprising polymethacrylate (Eudragit) polymers with a reasonable expectation of success. The simple substitution of one known element (liquid paraffin of Satturwar) for another (corn oil of Kim) to obtain predictable results (successful manufacture of an emulsion comprising polymethacrylate) is prima facie obvious. See MPEP 2143, Exemplary Rationale B.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ISAAC SHOMER/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612